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United States Patent and Trademark Office  
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Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,888,510. The application was filed on March 1, 2010, under 35 U.S.C. § 156. Please note that Applicant has also applied for patent term extension for U.S. Patent No. 5,670,373 and U.S. Patent No. 5,795,965 pursuant to 37 C.F.R. § 1.785 for BLA No. 125276/0 licensed January 8, 2010.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Stephen B. Maebius  
Foley & Lardner, LLP  
3000 K Street, NW  
Washington, DC 20007-5143

RE: ACTEMRA® (tocilizumab)  
Docket No. FDA-2010-E-0324